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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,299	02/06/2004	Brian Cox	388700-612-05-CIP2	5453

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EXAMINER	
MASHACK, MARK F	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
06/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/774,299	COX ET AL.	
	Examiner	Art Unit	
	MARK MASHACK	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22 and 25-28* is/are rejected.

7)☒ Claim(s) *23 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a communication dated 1/29/2010. Claims 1-28 are pending. Claims 1-12 have been withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/2010 has been entered.

Response to Arguments

2. Applicant's arguments filed 1/29/2010 have been fully considered but they are not persuasive. Applicant argues that “there is not ‘attachment’ or ‘coupling’ of the *Kupiecki* implant to its delivery catheter”. Examiner disagrees. Examiner asserts that using the catheter to delivery the filamentous endovascular device comprises “coupling” and a “releasable attachment”. The term “adjacent” is a relative term that does not define the metes and bounds of the claim limitations. Applicant argues that **Kupiecki** does not disclose “a substantial restriction to the flow of liquid". Examiner disagrees. Examiner asserts that providing the endovascular device in the catheter would

inherently provide a substantial restriction that the combination of saline and contrast medium would have a viscosity of “at least *about* 2cP".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 recites the limitation "the relative high viscosity liquid". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. **Claims 13-14, 17-21, 25-28** are rejected under 35 U.S.C. 102(b) as being anticipated by **Kupiecki et al. (“Kupiecki” US 5,669,931).**

Kupiecki discloses a method of deploying a filamentous endovascular davice into a target vascular site, comprising providing an elongate, flexible, hollow deployment tube **20** having a lumen (see Fig. 4); providing a filamentous endovascular device having a proximal end **24** and a coupling element **26** being releasably attached to the deployment tube adjacent the open distal end thereof, the coupling element being formed with a purge passage; (FIG 4A; the distal end of the device is considered the

"coupling element" and "formed with" only requires a relationship but the distal end of the device also has a helical purge passage extending through); purging air from the lumen by introducing a purging liquid through the lumen with a pressure sufficient to displace air from the lumen through the purge passage but not sufficient to separate the endovascular device from the deployment tube (Column 9, Line 57, - Column 10, Line 8); introducing the endovascular device intravascularly while it is attached to the deployment tube; separating the endovascular device from the deployment tube without radially expanding the deployment tube by injecting a liquid into the proximal end of the lumen (Column 10, Lines 10-26). An electric signal is produced in the method of visualization (Column 6, Liens 27-31). The deployment tube comprises a retention sleeve **64**. The saline is introduced prior to introducing the device to a patient (Column 10, Lines 57-66) and inherently reduces friction between said coupling element and said deployment tube. The coupling element comprises a water-soluble plug which would inherently soften in the presence of the purging liquid.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable **Rosenbluth et al. ("Rosenbluth" US 6,015,424)** in view of **Naglreiter (US 6,514,264)**

Rosenbluth discloses a method comprising providing an elongate, flexible, hollow deployment tube **16**; providing a filamentous endovascular device **12, 50** with a proximal end and the device **50** is provided with a coupling element (the distal end) formed with purge passage **62**; introducing the endovascular device intravascularly to the target site; and separating the endosvascular device from the deployment tube (Column 6, Lines 31-54, Column 6, Line 64, - Column 7, Line 8, Column 7, Lines 29-50). Examiner asserts that **Rosenbluth** does not disclose of any radially expansion of the deployment tube during the separating step. **Rosenbluth** does not explicitly disclose of the purging step. However, **Naglreiter** teaches of purging the lumen of air through a purge passage prior to introducing the device (Column 5, Lines 43-53). Given the teachings of **Naglreiter** it would have been obvious either embodiment of **Rosenbluth** modify the method by purging air from the coil in order to prevent introducing air into the vasculature.

10. **Claims 14 and 22** rejected under 35 U.S.C. 103(a) as being unpatentable over **Kupiecki** in view of **Goodson et al. ("Goodson" US 6,117,142).**

Kupiecki discloses all of the claimed limitations as disclosed above except for the steps of: (f) generating an electrical signal in response to the separation of the endovascular device from the deployment tube. However, **Goodson** teaches of a "very precise pressure monitoring system" for "measuring the hydraulic pressure applied by the syringe to disengage the embolic coil". "The pressure monitoring system provides a visual indication upon release of the embolic coil from the deployment system". Examiner asserts that electronic monitoring systems and/or digital visual indication systems are well known in the art at the time of the invention. Given the teachings of **Goodson**, it would have been obvious to provide an electronic signal in response to separation of the coil from the catheter in order to detect separation and prevent excessive injection of saline.

11. **Claims 14 and 22-24** rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenbluth** in view of **NagIreiter** as applied to Claim 13 in further view of **Eder (US 6,063,070)**.

Rosenbluth in view of **NagIreiter** disclose all of the claimed limitations as disclosed above except for the steps of: (f) generating an electrical signal in response to the separation of the endovascular device from the deployment tube. However, **Eder** teaches of deployed an indicator circuit to monitor the progression of the coil

detachment (Column 3, Lines 18-27). The coil would inherently be a component of the circuit and when the detachment of the coil would alter the circuit is some manner. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Eder**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of by generating an electrical signal in response of the separation of the endovascular device from the deployment tube. Doing so would provide feedback to the user of the separation.

12. **Claims 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kupiecki** in view of **Ressemann et al. ("Ressemann" US 6,224,609)**.

Kupiecki discloses all of the claimed limitations as stated above including the purge passage being dimensioned so as to provide a substantial restriction to the flow therethrough of a liquid having a viscosity greater than or equal to a predetermined viscosity. However, **Kupiecki** does not explicitly disclose the use of a contrast agent. However, **Ressemann** discloses that it is commonly known in the art to use a combination of saline and a contrast agent in order to visualize an area in the vasculature (Column 8, Lines 16-18). Examiner asserts that providing the endovascular device in the catheter would inherently provide a substantial restriction that the combination of saline and contrast medium would have a viscosity of "at least *about*

2cP". All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Ressemann**, it would have been obvious to provide a contrast agent with the saline of **Kupiecki** to provide assist in the tracking and visualization of the deployment device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773